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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,349

01/02/2007

Asa Rosenquist

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11/24/2008

SCULLY, SCOTT, MURPHY & PRESSER, P.C.

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EXAMINER

HA, JULIE

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

11/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,349

Applicant(s)

ROSENQUIST ET AL.

Examiner

JULIE HA

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 10-23, 36, 37, 40, 42-45, 47, 48 and 53-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 24-35, 38, 39, 41, 46 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

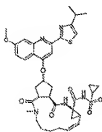
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/20/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Election/Restriction filed on July 21, 2008 is acknowledged. Claims 1-57 are pending in this application.

Restriction

1. Applicant's election with traverse of Group I (claims 1-54) and the election of



species in the reply filed on July 21, 2008 is acknowledged. The traversal is on the ground(s) that "PCT Rule 13.2 states that the unity of invention shall be fulfilled 'when there is a technical relationship among those inventions involving one or more or the same or corresponding special technical feature'...'The expression 'technical feature' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, make over the prior art." Applicant further argues that "Applicants should be given the opportunity to argue the merits during prosecution as to whether the claims are novel and obvious in relation to the prior art. Restriction of the claims based on the prior art at this stage would deny applicants such an opportunity. Furthermore...the International Search Report has not raised any issue on the basis for lack of unity of invention." Additionally, Applicant argues that "in accordance with MPEP 1850 and 37 CFR 1.475, there is unity of invention with respect to Groups 1, 2 and 3, since Group 1 is directed to a product;

Group 2 is drawn to a method of using the compound; and Group 3 is directed to a method of manufacture of the product." Furthermore, Applicant argues that "the rationale used by the USPTO does not support a restriction between Groups 1, 2 and 3...the Office Action has not met its burden in showing that the subject matter of Groups 1, 2, and 3 lack unity of invention." In regards to species election, Applicant argues that "the claimed compounds are similar in structure and are defined by the structure of Formula VI, such compounds are expected to have identical or similar chemical properties, mode of action, effects and reactive conditions. Thus, the compounds of Formula VI are not independent and distinct from each other." Applicant argues that "the subject matter in Formula VI relates to a single inventive concept under PCT Rule 13.2."

This is not found persuasive because due to the variables associated with the structure of formula VI, there is no core structure. In addition, the method claims lack unity of invention. The MPEP states the following regarding unity of invention of method claims: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the

process of Claim 1 ...,“ or “Process for the manufacture of the product of Claim 1 ...”). Similarly, a claim to one part referring to another cooperating part, for example, “plug for cooperation with the socket of Claim 1 ...”) is not a dependent claim (see MPEP 1850). Therefore, the method claims are in a different category: method of using the products. Therefore, these claims lack unity of invention.

In regards to the species election traversal, the species are patentably independent and distinct due to many different variables that lead to different and independent structures for each species. There is no clear core structure, since each variable has different components that can lead to different structures. For example, if q' is 1 and k is 2 then the compound of formula VI would have a 5 membered ring. However, if q' is 0 and k is 1, then the compound of formula VI would have a 3 membered ring. One would not anticipate the other. If R16 is H and G is O, this would not anticipate a compound wherein R16 is a C_6 alkyl and G is N-N. Furthermore, the search for each of the inventions is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case.

2. The requirement is still deemed proper and is therefore made FINAL. Claims 55-57 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Claims 4-5, 10-23, 36-37, 40, 42-45, 47-48 and 53-54 have been withdrawn from further consideration, as being drawn to nonelected species. A search was conducted on the

elect species, compound of Example 104, and this appears to be free of prior art. A search was extended to the broad Markush claim, and prior art was found. Claims 1-3, 6-9, 24-35, 38-39, 41, 46 and 49-52 are examined on the merits in this office action.

Rejection

35 U.S.C. 112, 2nd

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 6-9, 24-35, 38-39, 41 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1 recites, "R⁷ is J...R¹¹ is J...R^{7a} is J...Rx is H or C₁-C₅ alkyl; or Rx is J...Rd is H, C₁-C₃alkyl or Rd is J...R¹¹ is J; J, if present, is a single 3 to 10-membered saturated or partially unsaturated alkylene chain extending from the R⁷/R⁷ cycloalkyl, or from the carbon atom to which R⁷ is attached to one of Rd, Rj, Rx, Ry or R¹¹...Ry is H, C₁-C₃ alkyl; or Ry is J; one Rj is H and the other Rj is H or J..." It is unclear from the claims what J is, because, the variables are referring back to another variable, which refers back to itself. In other words, the variable appears to be circular, without specifying what J is. Because claims 2-3, 6-9, 24-35, 38-39, 41 and 46 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

6. Claim 1 recites the limitation "the Formula VI" in line 1 of claim 1. There is insufficient antecedent basis for this limitation in the claim. Formula VI is mentioned for the first time in claim 1, therefore, Formula VI recited in claim 1 lacks antecedent basis.

Rejection-35 U.S.C. 112, 1st

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 6-9, 24-35, 38-39, 41, 46 and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level

of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP 2163.

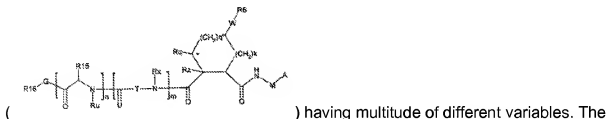
Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .”). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of

representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a compound of the formula VI



generic formula VI and variables do not describe a single structural feature, since there is no core structure being shared amongst the other compounds. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is broad generics with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of compounds, since there is no common core structure. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there

is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

The specification is limited to compound that belong to the same class of



compounds, those compounds all having a structure . The working examples



describe 157 Examples of compounds that share the common structure ,



and



. According to the broad generics of claim 1, there are multiple variables, and multiple components that are encompassed within those variables. The specification does not describe any other compounds having different variables for q' and k or all other variables. There are multiple components and variables that would lead to vast numbers of different compounds of formula VI. Description of compounds



having the structures

and



are not sufficient to encompass numerous other compounds of formula VI that belong to the same genus. For example, there are

varying structural components, varying organic compositions and components, and numerous distinct qualities that make up the genus. Again, due to the lack of common core structure shared by the compounds of formula VI, the specification does not describe sufficient amount of examples to encompass all of vast numbers of compounds encompassed by formula VI. Furthermore, since there are variables within the variables, for example R16, G, R15, Ru, n, U, R11, m, T, W, R8, M, A, R1, R2, R3, R4, R4', q', k and so on, there are vast numbers of compound possibilities of formula VI. Therefore, there is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

, which constitutes a species of the instant application.

The copending claims are drawn to wherein W is phenyl, naphthyl-1-yl, naphthyl-2-yl, pyrrol-1-yl etc (see claim 3); R^1 is $-OR^6$, wherein R^6 is C_{1-6} alkyl or hydrogen; or R^1 is $-NHS(=O)_2R^7$, wherein R^7 is methyl, cyclopropyl, or phenyl; or R^1 is $-NHS(=O)_2R^7$, wherein R^7 is methylcyclopropyl (see claim 5).

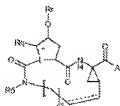
15. If one practiced the claimed invention of the instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa.

This is a provisional obviousness-type double patenting rejection.

16. Claims 1-3, 6-9, 24-35, 38-39, 41, 46, and 49-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 25 and 27 of copending Application No. 11/995900.

17. The instant claims are drawn to a compound of formula VI having multiple variables.

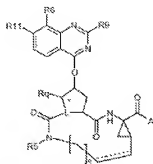
18. Claims 1-15, 25 and 27 of the copending application are drawn to a compound of



formula (I) , which constitutes a species of the instant application.

The copending claims are drawn to wherein A is OR^1 , $NHS(=O)_pR^2$, wherein R^1 is hydrogen, C_1 - C_6 alkyl, C_0 - C_3 alkylenecarbocyclyl, C_0 - C_0 alkyleneheterocyclyl; R^2 is C_1 - C_6 alkyl, C_0 - C_3 alkylenecarbocyclyl, C_0 - C_3 alkyleneheterocyclyl; p is independently 1 or

2...n is 3, 4, 5 or 6. Claim 8 is drawn to a compound of formula I that has the



structure:

wherein R⁹ is



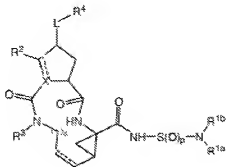
19. If one practiced the claimed invention of the instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa.

This is a provisional obviousness-type double patenting rejection.

20. Claims 1-3, 6-9, 24-35, 38-39, 41, 46, and 49-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-11 and 13-14 of copending Application No. 11/995835.

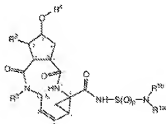
21. The instant claims are drawn to a compound of formula VI having multiple variables.

22. Claims 1-2, 4-11 and 13-14 of the copending application are drawn to a

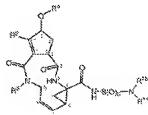


compound of formula (I), which constitutes a species of the instant application.

The copending claims are drawn to wherein X is N, CH and where X bears a double bond it is C; R^{1a} and R^{1b} are independently hydrogen; L is a direct bond, -O-, -O-C₁₋₄alkanedyl, -O-CO-, -O-C(=O)-NR^{5a}, or -O-C(=O)-NR^{5a}-C₁₋₄alkanedyl; n is 3, 4, 5, or 6; p is 1 or 2, etc (see claim 1). Claim 2 is drawn to a compound of claim 1 having the



formula (I-d):



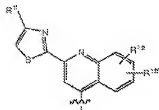
,or (I-e):

. Claim 6 is drawn

to a compound of claim 1 wherein L is -O- and R¹ is (d-1) a radical of



formula: . Claim 7 is drawn to a compound of formula (d-5-a) having the



structure:

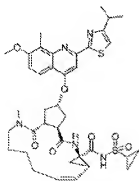
23. If one practiced the claimed invention of the instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa.

This is a provisional obviousness-type double patenting rejection.

24. Claims 1-3, 6-9, 24-35, 38-39, 41, 46 and 49-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending Application No. 11/632102.

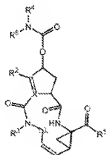
25. The instant claims are drawn to a compound of formula VI having multiple variables.

26. Claims 25-35 of copending application are drawn to a compound of

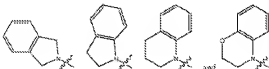


formula , which is a species of instant application.

27. If one practiced the claimed invention of the instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa.
28. Claims 1-3, 6-9, 24-35, 38-39, 41, 46, and 49-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8-9 of copending Application No. 11/995869.
29. The instant claims are drawn to a compound of formula VI having multiple variables.
30. Claims 1-6 and 8-9 of the copending application are drawn to a compound of



formula (I) , wherein R^4 and R^5 taken together form the structures


of
31. If one practiced the claimed invention of the instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa.

This is a provisional obviousness-type double patenting rejection.

Conclusion

32. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/J. H./
Examiner, Art Unit 1654